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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,325	02/14/2002	Robert Bartlet Elliott	011115	3318

22876 7590 03/24/2003

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,325

Applicant(s)

ELLIOTT ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 110-151 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372.

Group I. Claims 110-125, drawn to a method for preparing a porcine islet.

Group II. Claims 126-151, drawn to a method of making an encapsulated composition comprising porcine islet cells, glucose, insulin porous, and a suitable alginate in ultra pure form; and a method for treating a mammalian patient suffering from diabetes using the encapsulated composition.

2. The invention listed as groups I-II do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I differs from group II in that they are different methods for preparing different products. The materials used in the method of group II, such as insulin porous and alginate gel encapsulating materials, are not required in the method of group I. The methods have different inventive steps, generate different products and use different starting materials. 37 CFR 1.475 (b) states "AN INTERNATIONAL OR A NATIONAL STAGE APPLICATION CONTAINING CLAIMS TO DIFFERENT CATEGORIES OF INVENTION WILL BE CONSIDERED TO HAVE UNITY OF INVENTION IF THE CLAIMS ARE DRAWN ONLY TO ONE OF THE FOLLOWING COMBINATIONS OF CATEGORIES: (1) A PRODUCT AND A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF SAID PRODUCT; OR (2) A PRODUCT AND A PROCESS OF USE OF SAID PRODUCT; OR (3) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND A USE OF THE SAID PRODUCT;

OR (4) A PROCESS AND AN APPARATUS OR MEANS SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS; OR (5) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND AN APPARATUS OR MEANS SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS.” Since multiple processes of making different products are claimed, unity of invention is lacking and restriction is required.

Moreover, as cited in the International Preliminary Examination Report, Group II, but not group I is anticipated or obvious over the cited prior art of record, WO 99/49734. Applicants are advised to see 37 CFR 1.475 (a)-(d) for details. 37 CFR 1.475 (a) recites “AN INTERNATIONAL AND A NATIONAL STAGE APPLICATION SHALL RELATED TO ONE INVENTION ONLY OR TO A GROUP OF INVENTIONS SO LINKED AS TO FORM A SINGLE GENERAL INVENTIVE CONCEPT (‘REQUIREMENT OF UNITY OF INVENTION’). WHERE A GROUP OF INVENTIONS IS CLAIMED IN AN APPLICATION, THE REQUIREMENT OF UNITY OF INVENTION SHALL BE FULFILLED ONLY WHEN THERE IS A TECHNICAL RELATIONSHIP AMONG THOSE INVENTIONS INVOLVING ONE OR MORE OF THE SAME OR CORRESPONDING SPECIAL TECHNICAL FEATURES.” The expression “special technical features” shall mean those technical features that define a contribution, which **each** of the claimed inventions, considered **as a whole**, makes over the prior art. Consequently, the special technical feature of group II does not provide a contribution over the prior art as a whole with groups I, so unity of invention is lacking.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

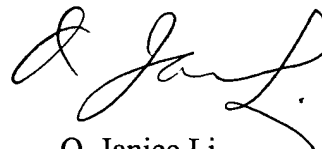
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
March 17, 2003